

## **REMARKS**

### **Status**

Claims 1-41 were originally filed with the application. The present amendment cancels claims 15-17 and adds new claim 42. Accordingly, it is claims 1-14 and 17-42 which are at issue.

### **The Rejection**

Claims 6, 18 and 25 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claims 1-5, 13-17, 20-23, 27, 31-32 and 34-35 have been rejected under 35 U.S.C. §102(b) as being anticipated by Shaw et al. (US 5,678,572). Claims 7, 19, 24 and 36-41 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Shaw et al. Claims 8-9, 11-12 and 26 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Shaw et al. in view of Armstrong (US 2002/0111639). Claims 28-30 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Shaw et al. in view of Nobles et al. (US 2002/0013601). Claim 10 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Shaw et al. in view of Armstrong and further in view of Flack (US 1,267,066). Finally, claim 33 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Shaw et al. in view of Nobles et al. and further in view of Addis (US 6,656,154).

### **Remarks Directed to the Rejection of Claims 6, 18 and 25 under 35 U.S.C. §112, Second Paragraph**

Regarding claim 6, Applicant has amended the claim such that the term “the stressed position” is clearly associated with the collapse position.

Regarding claim 18, this claim has been amended such that the term “minimised” has been deleted and as such Applicant respectfully submits that the claim is no longer indefinite.

Regarding claim 25, the term “the shape memory alloy” has been replaced with the term “a shape memory alloy”. As such, this term no longer has insufficient antecedent basis.

**Remarks Directed to the Rejection of the Claims under §102(b) and §103(a)**

Claims 15-17 have been cancelled.

Independent claim 1 has been amended such that the apparatus has a guide member that defines a leading end and an aperture in the guide member defining an area for access from the apparatus into the body passage. At least part of the access area is spaced from a leading end and a pair of expansion arms are included and adapted to extend across respective edge regions of the aperture in the guide member to be moved between a collapsed position and an expansion position by controllably elastically deforming said expansion arms to expand the body passage in the region of the aperture.

In the Office Action mailed November 9, 2009, the Examiner interpreted openings between the stays of the embodiment of Figures 1-3d of Shaw et al. as access areas. However, Shaw et al. does not teach or suggest a guide member with an aperture defining an access area and at least part of the access area spaced from the leading end. In addition, the embodiment of Figures 1-3d or the embodiment of Figures 4a-4d does not teach or suggest a pair of expansion arms that are adapted to extend across respective edge regions of an aperture. As such, Applicant respectfully submits that independent claim 1 and all claims depending thereon are no longer anticipated under 35 U.S.C. §102(b) or obvious under 35 U.S.C. §103(a).

In addition, providing a pair of expansion arms adapted to extend across respective edge regions of the aperture is advantageous in at least that it ensures that the access area is

uninterrupted and that the maximum width of the access area can be increased, as described on page 17, lines 13-22 and Figures 7, 8, 9, 25 and 26 of the application as filed. Extension across the respective edge regions ensures that the access area is uninterrupted. Additionally, a feature, such as a tumor, can be maintained in the same position relative to the longitudinal axis of the device while the body passage is expanded by the pair of expansion arms, thereby aiding viewing of and access to the feature. Arms adapted to extend across respective edge regions of the aperture can also aid to support tissue on either side of such a feature, which is particularly beneficial should a procedure such as a biopsy or surgery be required.

Independent method claim 34 has been amended similarly to independent claim 1 to include “inserting a guide member with an aperture” and “elastically deforming a pair of expansion arms extending across respective edge regions of the aperture, to expand the body passage in the region of the aperture”. For the same reasons as stated above for independent claim 1, Applicant respectfully submits that independent claim 34 and all claims depending thereon are no longer anticipated under 35 U.S.C. §102(b) or obvious under 35 U.S.C. §103(a).

New claim 42 recites that the activating member of claim 8 is configured to move the arms simultaneously. Moving the arms simultaneously provides improved control and further differentiates the present invention from Shaw et al. where it is noted “that each stay is separately pushed forward” (column 2, lines 39-40).

Furthermore, Applicant respectfully asserts that a device according to Shaw et al. merely provides axial access through the device, and does not have a guide member defining a leading end, with an aperture in the guide member defining an area for access from the apparatus into the body passage, at least part of the area spaced from the leading end, as disclosed in claim 1 of the current application. The axial nature of the access of the devices of Shaw et al. is indicated in

column 2, lines 57-62, where it is stated that the flexible stays may be replaced by a hollow tube. Since the flexible stays are interchangeable with a hollow tube, it is clear that no access area is provided with at least part of the area spaced from the leading end. Further confirmation of the purely axial access provided by Shaw et al. is provided in column 1, lines 54-57 where it is cited “Another object of the present invention is to provide a hollow cylinder that may be used to extend a laparoscope into an operation area and may provide a passage for a scalpel, clip, etc. extending into the body for treatment.” and in the single claim “... wherein an internal passage is formed within said sleeve member to receive a laparoscope ...”. The disadvantages of such restricted access are described in the background section of the current application on page 2, lines 4-8.

Shaw et al. also fails to disclose the feature of claim 20, namely that the access area is an opening extending around at least half of a perimeter of the guide member. The figures clearly show that any openings between the stays do not extend further than a quarter of the perimeter – the stays are spaced at 90 degree intervals.

Applicant further asserts that claim 10 has been incorrectly rejected as it would not have been obvious to combine features of Shaw et al. with features of Armstrong et al. and Flack et al. Using the screw mechanism of Flack et al. in combination with a device based on Shaw et al. and Armstrong et al. would result in a device with a screw wheel blocking access through the device. It would therefore not have been obvious to combine these features in a medical device where such access is essential. Furthermore, since access to the body passage would be prevented, the resultant device would not correspond to that of claim 10.

Claim 33 also appears to have been incorrectly rejected since the pressure gauge of Addis et al. measures pressure in a balloon, while claim 33 measures an expansion force of a device

with expansion arms and no balloon. Measuring the expansion force of expansion arms clearly differs from measuring the internal fluid pressure of a balloon.

In summary, all of the pending claims are submitted to be in allowable form.

### **Conclusion**

In view of the amendments and remarks presented herein, Applicant respectfully submits that all claims are now in condition for allowance. Any questions, comments, or suggestions the Examiner may have which would place the application in still better condition for allowance should be directed to the undersigned attorney.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 07-1180.

Dated: 04/07/2010

Respectfully submitted,

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